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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/753,313	12/29/2000	Gerardo Castillo	PROTEO.P16	1184

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EXAMINER

JIANG, SHAOJIA A

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 10/21/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/753,313

Applicant(s)

CASTILLO ET AL.

Examiner

Shaojia A Jiang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 August 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4,5,10-13 and 15-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4,5,10-13 and 15-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

This Office Action is a response to Applicant's amendment and response filed on August 1, 2003 in Paper No. 13 wherein claims 1-3, 6-9, 14, and 24-27 are cancelled, and claims 4, 22, and 23 have been amended.

Currently, claims 4-5, 10-13 and 15-23 are pending in this application.

Applicant's declaration of Dr. Alan D. Snow (inventor), submitted August 1, 2003 in Paper No. 13 under 37 CFR 1.132, is acknowledged and will be further discussed below.

Applicant's amendment filed on August 1, 2003 in Paper No. 13 with respect to the rejection of claim 4-5 and 10 made under 35 U.S.C. 112 second paragraph for the use of the indefinite expressions, i.e., "other amyloidoses" in claim 4 of record stated in the Office Action dated January 28, 2003 have been fully considered and found persuasive to remove the rejection as to claim 4 since the phrase "other amyloidoses" has been deleted from the claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for the same reasons of record stated in the Office

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Action dated January 28, 2003. Applicant's amendment and remarks submitted August 1, 2003 in Paper No. 13 have been considered but not found persuasive.

As indicated in the previous Office Action, claim 10 recites the limitation "plant materials" in the second line of the claim. There is insufficient antecedent basis for this limitation in the claim since claim 4 does not recite the phrase "plant materials".

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 22-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for the same reasons of record stated in the Office Action dated January 28, 2003. Applicant's amendment and remarks submitted August 1, 2003 in Paper No. 13 have been considered but not found persuasive.

As indicated in the previous Office Action, Claims 22-23 provide for the use of a source of green tea..., but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 22-23 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under

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35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Applicant is suggested to remove the phrase, "The use of".

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 4-5, 10-12 and 19-23 are rejected under 35 U.S.C. 112, first paragraph, for scope of enablement because the specification, while being enabling for the treatment, inhibition, or management of amyloid fibril formation, deposition, accumulation or aggregation in Alzheimer's disease disclosed in the specification employing the instant compounds herein, does not reasonably provide enablement for the prevention or preventing amyloid fibril formation, deposition, accumulation or aggregation in Alzheimer's disease by employing the plant material, green tea, for the same reasons of record stated in the Office Action dated January 28, 2003. Applicant's amendment and remarks submitted August 1, 2003 in Paper No. 13 have been fully considered but not found persuasive.

As discussed in the previous Office Action, The instant claims are drawn to the methods for the prevention of or preventing amyloid fibril formation, deposition, accumulation or aggregation in Alzheimer's disease in a human or animal. The instant

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specification fails to provide information that would allow the skilled artisan to practice the instant invention. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

(1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

Nature of the invention: The instant invention pertains to the method the prevention of amyloid fibril formation, deposition, accumulation or aggregation in Alzheimer's disease in a human or animal.

The state of the prior art: The skilled artisan would view that the treatment to prevent amyloid fibril formation, deposition, accumulation or aggregation in Alzheimer's disease in a human or animal totally, absolutely, or permanently, is highly unlikely, not even occurring at the first time.

The relative skill of those in the art: The relative skill of those in the art is high.

The predictability or lack thereof in the art: The skilled artisan would view that the treatment to prevent amyloid fibril formation, deposition, accumulation or aggregation in Alzheimer's disease in a human or animal totally, absolutely, or permanently is highly unpredictable, and not even occur at the first time is highly unpredictable.

The amount of direction or guidance presented and the presence or absence of working examples: In the instant case, no working examples are presented in the specification as filed showing how to prevent amyloid fibril formation, deposition, accumulation or aggregation in Alzheimer's disease in a human or animal totally, absolutely, or permanently, not even occurring at the first time. Applicant asserts that working examples are never a statutory requirement in such a specification. Lack of a working example, however, is a factor to be considered, especially in a case involving an unpredictable and undeveloped art. See MPEP 2164. As discussed above, preventing amyloid fibril formation, deposition, accumulation or aggregation in Alzheimer's disease in a human or animal totally, absolutely, or permanently is highly unpredictable and unlikely, and not even occur at the first time is highly unpredictable.

Moreover, the standard for determining whether the specification meets the enablement requirement was cast in the Supreme Court decision of *Mineral Separation v. Hyde*, 242 U.S. 261, 270 (1916) which postured the question: is the experimentation needed to practice the invention undue or unreasonable? That standard is still the one to be applied. In *re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). Accordingly, even though the statute does not use the term "undue experimentation," it has been interpreted to require that the claimed invention be enabled so that any person skilled in the art can make and use the invention without undue experimentation. In *re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988). See also *United States v. Telectronics, Inc.*, 857 F.2d 778, 785, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988) ("The test of enablement is whether one reasonably skilled in the art could make or use

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the invention from the disclosures in the patent coupled with information known in the art without undue experimentation.”). See MPEP 2164.

Genentech, 108 F.3d at 1366, states that “a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion” and “[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable”.

Therefore, in view of the Wands factors, e.g., the amount of direction or guidance provided, absence of working examples, and the predictability of the art discussed above, to practice the claimed invention herein, a person of skill in the art would have to engage in undue experimentation to test all compounds encompassed in the instant claims and their combinations to be administered to a host employed in the claimed methods of the particular treatments herein, with no assurance of success.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 4-5, 10-13 and 15-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Castillo et al. (WO 98/51302 of record) for the same reasons of record stated in the Office Action dated January 28, 2003.

Castillo et al. discloses that *Uncaria tomentosa* plants and their extracts (known containing common flavanols such as catechins including epicatechin, and gallic catechin), are useful in methods of treatment, prevention, or management of an amyloidosis or amyloid formation, deposition, accumulation in a mammal. See abstract, pages 1-3 specially page 2 lines 23-24, page 3 lines 21-23 and 31-33, page 6 lines 30-31, page 9 lines 12-14, page 12 lines 12-14, and claim 6. Castillo et al. also discloses the employment of an additional agent from the plant materials herein (see page 4 and 9).

Thus, Castillo et al. anticipates claims 4-5, 10-13 and 15-21.

Applicant's amendment and remarks submitted August 1, 2003 in Paper No. 13 have been fully considered but they are not deemed persuasive to render the claimed invention patentable over the prior art because *Uncaria tomentosa* plants, known green teas, and their extracts are well known to contain common flavanols such as catechin, epicatechin, and gallic catechin in the art. Applicant is requested to note that the green tea or *Uncaria tomentosa* composition of Castillo et al. inherently comprises common flavanols such as catechin, epicatechin, and gallic catechin since catechins are known to encompass these compounds which are known to be isolated from green tea (Yoshiko Sugita-Konishi et al. *Biochimica et Biophysica Acta*. 1472, (1999), 42-50, PTO-1449 provided by Applicant, supports the examiner's position that green teas, and their extracts are well known to contain common flavanols such as catechin, epicatechin, and gallic catechin).

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Claims 4-5, 10-13 and 15-21 are rejected under 35 U.S.C. 102(b) as being anticipated by JP 10245342 (of record) for the same reasons of record stated in the Office Action dated January 28, 2003.

Claims 4-5, 10-13 and 15-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Shin-Ya et al., (of record) for the same reasons of record stated in the Office Action dated January 28, 2003.

Applicant's remarks and the declaration of Dr. Alan D. Snow with respect to Wang's reference for the argument of no inherency have been fully considered but not found persuasive since the declaration primarily discusses that the mechanism of action of the treatment proposed by Wang. As discussed in the previous Office, the mechanism of action of a treatment does not have a bearing on the patentability of the invention if the method steps are already known. Moreover, the instant methods are not limited to the mechanisms in Wang. The declaration herein is ineffective to overcome the 102(b) rejections herein.

As discussed in the previous Office, even though Applicant's recitation of a new mechanism of action for the prior art method will not, by itself, distinguish the instant claims over the prior art teaching the same or nearly the same method steps. Mere recognition of latent properties in the prior art does not render novel or nonobvious an otherwise known invention. See *In re Wiseman*, 201 USPQ 658 (CCPA 1979).

Regarding the doctrine of inherency. See *Eli Lilly and Co. v. Barr Laboratories Inc.* 251 F3d. 955; 58 USPQ2d 1869-1881 (Fed. Cir. 2001).

In view of the rejections to the pending claims set forth above, no claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (703) 305-1008. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-1235.

S. Anna Jiang, Ph.D.
Patent Examiner, AU 1617
October 8, 2003


SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER

10/28/03